



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS-5540-NC]

RIN 0938-AV19

Request for Information; Episode-based Payment Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health of Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information seeks input from the public regarding the design of a future episode-based payment model. Responses to this request for information may be used to inform potential future rulemaking or other policy development.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 30 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-5540-NC.

Comments, including mass comment submissions, must be submitted in *one* of the following three ways (please choose only *one* of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address **ONLY**:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-5540-NC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5540-NC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sacha Wolf, (410) 786-9769 (Sacha.Wolf@cms.hhs.gov), for issues related to incentive structure, model overlap, and BPCI Advanced.

Lauren Vanderwerker (Lauren.Vanderwerker@cms.hhs.gov) for issues related to payment and Comprehensive Care for Joint Replacement (CJR).

Nicholas Adcock (Nicholas.Adcock@cms.hhs.gov) for issues related to health equity.

Dena McDonough (Dena.McDonough@cms.hhs.gov) for issues related to quality measures, clinical episodes, or any other issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that Web site

to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

In 2021, the Innovation Center announced a strategic refresh with a vision of having a health care system that achieves equitable outcomes through high quality, affordable, person-centered care.¹ To guide this updated vision, the Innovation Center intends to design, implement, and evaluate future episode-based payment models with a focus on five strategic objectives, including advancing health equity and driving accountable care.² With a bold goal of having 100 percent of Medicare fee-for-service (FFS) beneficiaries and the vast majority of Medicaid beneficiaries in an accountable care relationship by 2030, we acknowledge that additional opportunities for accountable care relationships with specialists are needed.³

One approach to support accountable care and to create an avenue for specialists to participate in value-based care initiatives is through episode-based payment models. The Innovation Center has launched several episode-based payment models (also known as bundled-payment models), four of which are either ongoing or being implemented in 2023.⁴ These models help to address the inefficiencies in traditional Medicare FFS, where providers are paid for each item or service, which may drive volume over value and fragment care. By bundling

¹ CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation - A Strategy for the CMS Innovation Center's Second Decade (<https://innovation.cms.gov/strategic-direction-whitepaper>).

² The five strategic objectives are Drive Accountable Care, Advance Health Equity, Support Innovation, Address Affordability, and Partner to Achieve System Transformation.

³ Providers in accountable care relationships work together and with their patients to manage patients' overall health, all while considering their patients' personal health goals and values.

⁴ CMS Innovation Center models still ongoing or being implemented in 2023 are the Bundled Payments for Care Improvement Advanced Model, Comprehensive Care for Joint Replacement Model, Enhancing Oncology Model, and the End-Stage Renal Disease Treatment Choices Model.

items and services into an episode of care, providers are better incentivized to coordinate patient care and to avoid duplicative or unnecessary services.

Early episode-based payment demonstrations were narrow in scope and assessed particular design aspects, such as the use of gainsharing mechanisms or bundled payments for inpatient stays.⁵ Current models build upon early tests by examining condition-specific or acute inpatient/outpatient episodes with accountability usually extending 90-days beyond the triggering event. Generally, these episode-based payment models have demonstrated reductions in gross Medicare spending, driven in large part by reductions in post-acute care (PAC) spending or utilization, with minimal to no change on quality of care.⁶

The Innovation Center is utilizing lessons learned from our experience with the Bundled Payments for Care Improvement (BPCI), Bundled Payments for Care Improvement Advanced (BPCI Advanced), and the Comprehensive Care for Joint Replacement (CJR) models to design and implement a new episode-based payment model focused on accountability for quality and cost, health equity, and specialty integration. To further inform development of the potential new model, we are soliciting input from those with additional insight and frontline experience with bundled payments. This request for information (RFI) is not seeking feedback on models which address particular conditions over a longer period of time, such as the Enhancing Oncology Model and the Kidney Care Choices Model. Specifically, we are requesting input on a broader set of questions related to care delivery and incentive structure alignment and six foundational components:

- Clinical Episodes
- Participants

⁵ The Medicare Hospital Gainsharing Demonstration (<https://innovation.cms.gov/innovation-models/medicare-hospital-gainsharing>) and Physician Hospital Collaboration Demonstration (<https://innovation.cms.gov/innovation-models/physician-hospital-collaboration>) focused on gainsharing while the Medicare Acute Care Episode Demonstration (<https://innovation.cms.gov/innovation-models/ace>) tested a global payment for certain inpatient stays.

⁶ Synthesis of Evaluation Results Across 21 Medicare Models (<https://innovation.cms.gov/data-and-reports/2022/wp-eval-synthesis-21models>).

- Health Equity
- Quality Measures, Interoperability, and Multi-Payer Alignment
- Payment Methodology and Structure
- Model Overlap

In addition to maintaining or improving quality of care and reducing Medicare spending (two requirements articulated in the Innovation Center statute⁷), CMS intends to test an episode-based payment model with goals to:

- Improve care transitions for the beneficiary; and
- Increase engagement of specialists within value-based, accountable care.

We recognize that for these goals to be realized, there must be a change in how episode-based payment models coexist with population-based Medicare Accountable Care Organizations (ACOs). In theory, ACOs and episode-based payment models should be complementary, as ACOs are well situated to prevent unnecessary care, while episode-based payment model participants focus on controlling the cost of acute, high-cost episodes. However, these value-based care approaches have not consistently been complementary and, in some cases, have complicated health care operations.

The Innovation Center strategic refresh provides an opportunity to better align episodes of care and population-based models to improve the beneficiary experience and reduce health care inefficiencies.⁸ Furthermore, coordination capitalizes on the strengths of each provider, allowing them to manage and influence the outcomes that they control. Unfortunately, the current ACO and episode-based payment environment has created the perception that certain providers and suppliers are striving for the same cost savings, and uncertainty with respect to who manages a beneficiary's care. This issue is further exacerbated by complex model overlap

⁷ Statutory requirements for CMS Innovation Center models are covered in section 1115A of the Social Security Act.

⁸ Ryan, A. M., Krinsky, S., Adler-Milstein, J., Damberg, C. L., Maurer, K. A., & Hollingsworth, J. M. (2017). Association Between Hospitals' Engagement in Value-Based Reforms and Readmission Reduction in the Hospital Readmission Reduction Program. *JAMA internal medicine*, 177(6), 862–868. <https://doi.org/10.1001/jamainternmed.2017.0518>.

policies that have changed as models and initiatives have evolved over time. These unintended consequences may discourage providers from participating in alternative payment models (APMs), leading to fewer beneficiaries under accountable care relationships. In order for the Innovation Center to achieve its strategic policy goals, episode-based payment incentives must be aligned across models to encourage intentional overlap, promote coordination, and facilitate seamless transition back to primary care.

II. Solicitation of Public Comments

The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) seeks feedback regarding a potential new episode-based payment model that would be designed with a goal to improve beneficiary care and lower Medicare expenditures by reducing fragmentation and increasing care coordination across health care settings. The Innovation Center is releasing this request for information (RFI) to gather feedback on testing a new model design, built on previous experience with episode-based payment models, and to further the goals of improved outcomes and reduced Medicare spending. Whenever possible, respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses.

We anticipate this model would require participation by certain entities, such as Medicare providers or suppliers or both located in certain geographic regions, to ensure that a broad and representative group of beneficiaries and participants are included. Further, requiring participation would also help to overcome voluntary model challenges such as clinical episode selection bias and participant attrition. Therefore, any such model would be implemented via notice and comment rulemaking, with ample opportunity for public input. We expect this episode-based payment model to be implemented no earlier than 2026, ensuring participants have sufficient time to prepare for the model.

A. Care Delivery and Incentive Structure Alignment

Interested parties and experts have requested that CMS align specialty care incentives with population-based model initiatives to improve coordination across the continuum of care.⁹ In November 2022, the Innovation Center released its comprehensive specialty strategy to test models and innovations supporting access to high-quality, integrated specialty care across the patient journey—both longitudinally and for procedural or acute services.¹⁰ One element of the strategy is to maintain momentum established by episode-based payment models.

To date, the Innovation Center’s episode-based payment models have focused largely on acute inpatient and hospital outpatient episodes, through CJR, BPCI, and BPCI Advanced. These model tests have successfully driven essential care delivery changes to transform how patients transition between hospitals and post-acute care providers.¹¹ Through this next model, CMS will build on those care improvements to better align episodic and longitudinal, population-based incentives, thereby strengthening communication, collaboration, and coordination across providers at all points of a patient’s journey through the health care system. This will be achieved through design features such as considering a shorter, 30-day episode to support coordination, while limiting overlap.

To maintain momentum among providers and health systems, CMS extended the original CJR model for an additional 3 performance years (October 1, 2021- December 31, 2024), with modifications to certain elements such as the episode definition and the payment methodology. Subsequently, CMS extended BPCI Advanced for 2 years (January 1, 2024- December 31, 2025), with technical changes to the pricing methodology to balance participation incentives

⁹ Care coordination is a key concept for episode-based and population-based initiatives. Please see the CMS Innovation Center’s Care Coordination page (<https://innovation.cms.gov/key-concept/care-coordination>) for further details.

¹⁰ The CMS Innovation Center’s Strategy to Support Person-centered, Value-based Specialty Care (<https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care>).

¹¹ Comprehensive Care for Joint Replacement Model: Fourth Evaluation Report (<https://innovation.cms.gov/data-and-reports/2021/cjr-py4-annual-report>); BPCI Advanced: Fourth Annual Report (<https://innovation.cms.gov/data-and-reports/2023/bpci-adv-ar4>).

with statutory requirements. The extension requires new convener participants to be Medicare-enrolled providers or suppliers or ACOs, which will support increasing ACO management of specialty conditions and primary care integration. In addition, the future data transparency initiatives of the specialty strategy will provide ACOs tools to better manage specialty care for patients within their population.¹²

The Innovation Center acknowledges that the role of clinical episodes will grow and evolve as more patients are cared for by providers in accountable care arrangements. To help us ensure all accountable entities provide patients with the highest value care, we seek input on the following questions:

- How can CMS structure episodes of care to increase specialty and primary care integration and improve patient experience and clinical outcomes?
- How can CMS support providers who may be required to participate in this episode-based payment model?
- How can CMS ensure patient choice and rights will not be compromised as they transition between health care settings and providers?
- How can CMS promote person-centered care in episodes, which includes mental health, behavioral health, and non-medical determinants of health?
- How can CMS support multi-payer alignment for providers and suppliers in episode-based and population-based models?
- For population-based entities currently engaging specialists in episodic care management, what are the key factors driving improvements in cost, quality, and outcomes?
- How does the nature of the relationship (that is, employment, affiliation, etc.) between a population-based entity and a specialist influence integration?

¹² CMS has signaled its intent to provide data on specialist performance, such as shadow bundles, to facilitate integration with ACOs. Shadow bundles would use existing ACO-attributed lives and claims data to assign services and associated payments to clinical episodes and enable a more nuanced view of performance on procedural or condition specific care.

- What should CMS consider in the design of this model to effectively incorporate health information technology (health IT) standards and functionality, including interoperability, to support the aims of the model?

- How can CMS include home and community-based interventions during episode care transitions that provide connections to primary care or behavioral health and support patient independence in home and community settings?¹³

B. Clinical Episodes

The CJR and BPCI Advanced models test condition-specific medical or surgical episodes, or both, which are initiated by either an inpatient hospitalization or a hospital outpatient procedure and include items and services provided over the following 90-day period.¹⁴

Many factors, including Medicare savings potential, are considered when deciding which clinical episode categories a model will test. Currently, there is no single clinical episode or service line group that meets every priority, but each is considered against the following criteria.

- Clinical homogeneity: Episodes with high clinical homogeneity may simplify target price methodology and make it easier to identify included items and services.
- Spending variability: Episodes with greater spending variability suggest opportunities for reducing costs and improving health care efficiency.
- Episode volume: Episodes with sufficient volume reduce pricing volatility and may spread financial risk.
- Quality impacts: Episodes with established quality measures or positive health equity outcomes may improve beneficiary quality of care.
- Episode overlap alignment: Episodes that support ACO collaboration.

¹³ For example, Community Aging In Place, Advancing Better Living for Elders (CAPABLE) was a CMS Health Care Innovation Award project (<https://downloads.cms.gov/files/cmimi/hcia-chspt-thirdannualrpt.pdf>) that supported home-based care management by a registered nurse and occupational therapy to improve functional status. Services included home safety assessments, education, problem solving, care coordination, and handyman services to address housing-related safety risks.

¹⁴ Medical episodes are those requiring medical management of an acute exacerbation of a condition whereas surgical episodes are those requiring a procedural intervention.

CJR tests a single surgical episode category, while BPCI Advanced includes 34 medical and surgical episode categories. Beginning in 2021, the BPCI Advanced model combined the individual clinical episodes into eight service line groups to expand participant accountability and promote efficiencies across similar episodes. While participants acknowledged the potential benefits of this change for increasing episode volume, they highlighted the difficulties of redesigning care processes across certain medical and critical care service lines. They found identifying and implementing care redesign interventions to be more straightforward for surgical episodes. CMS' BPCI Advanced evaluation reflected this; reductions in episode payments were more substantial for surgical episodes compared to medical episodes¹⁵ and suggest early management may reduce Medicare spending.

CMS maximizes the items and services included in a clinical episode to align with a total cost-of-care approach and ensure providers have accountability for all related aspects of care. This total cost-of-care approach represents an opportunity for improved care coordination and collaboration across disciplines and settings. For example, participants are generally accountable for the anchor event, along with PAC, hospital readmissions, physician, laboratory, and durable medical equipment costs.¹⁶ Although exclusion lists omit items and services that are clearly unrelated to the anchor event, clinical subjectivity does exist, and participants have expressed concern that they have limited influence over some included items and services.

The 90-day episode length has demonstrated success in reducing PAC spending, but the extended duration of overlap between episode-based payment models and ACO initiatives may contribute to inefficiencies. Reducing episode duration to 30 days could both sustain the

¹⁵ In the BPCI Advanced: Fourth Annual Report (<https://innovation.cms.gov/data-and-reports/2023/bpci-adv-ar4>), the reduction in per-episode payments was larger for surgical clinical episodes than medical clinical episodes (-\$796 or -3.1 percent for medical clinical episodes vs. -\$1,800 or -5.8 percent for surgical clinical episodes).

¹⁶ Items and services typically included in a clinical episode include inpatient/outpatient hospital services, post-acute care services, laboratory services, durable medical equipment, Medicare Part B drugs, physician services, and mental health services. Items and services typically excluded from a clinical episode include certain readmissions (for example, transplant or cancer), blood clotting factors, new technology add-on payments, and transitional pass-through payments.

spending reductions and mitigate some of the current challenges. Specifically, a 30-day episode would position the specialist as the principal provider near the anchor event with a hand off back to the primary care provider for longitudinal care management.

We anticipate this next episode-based payment model would test a set of clinical episodes that is broader than CJR, but narrower than BPCI Advanced, with shorter episode lengths. We request feedback on the following clinical episode questions:

- Which of the clinical episode categories, tested in either BPCI Advanced or CJR, should be considered for, or excluded from, this next episode-based payment model?¹⁷
- Should CMS test new clinical episode categories?
- How many clinical episode categories or service line groupings should be tested?
- Should CMS consider alternatives to a 30-day episode length? If so, include evidence to support this marker as the most appropriate transition point from the hospital to the primary care provider.
- Which clinical episodes are most appropriate for collaboration between episode-based model participants and ACOs?
- Are there particular types of items or services that should be excluded from clinical episodes?
- Are there other considerations for selection criteria that are of interest to other payers?
- Aside from episode selection, reducing the duration of an episode of care, and the types of services in an episode, what other ways can CMS prevent unnecessary overlap with ACO functions?
- For which clinical episodes are ACOs better positioned than episode-based payment model participants to efficiently manage care?

¹⁷ The CJR model only tests the lower extremity for joint replacement episode, which includes MS-DRGs 469, 470, 521, 522 and CPT codes 27447 and 27130. The BPCI Advanced model tests 34 clinical episode categories which can be found here: <https://innovation.cms.gov/media/document/bpci-adv-clin-ep-lists-my6-mar2023>.

- Should different participants be accountable for different clinical episodes? For example, if both hospitals and physician group practices (PGPs) are participants in the episode-based payment model, should hospitals be accountable for a certain clinical episode category (for example, congestive heart failure) or a certain clinical episode type (for example, medical episodes vs. surgical episodes) as compared to PGPs?

C. Participants

A key component of any APM is defining model participants. For episode-based payment models, the participant generally assumes accountability for cost and quality performance. Often, the type and setting of clinical episodes will dictate who is eligible to participate. The ability to bear financial risk, availability of resources, prior value-based care experience, and downstream entities may inform participant eligibility. Participant eligibility differed between BPCI Advanced and CJR, and other entities have also expressed interest in being participants in future episode-based payment models.

1. BPCI Advanced Participants

The BPCI Advanced model has convener and non-convener participants. A convener bears and apportions financial risk and facilitates coordination among one or more “downstream episode initiators.” In contrast, a non-convener participant bears financial risk only for itself and does not have any downstream episode initiators. Non-convener participants and downstream episode initiators must be either an acute care hospital or PGP.

Convener participants have generally been the dominant participant type in BPCI Advanced. Conveners provide support such as analytics, care navigators, and administrative assistance to their downstream episode initiators, who otherwise may not have joined the model. However, this arrangement was challenging for some hospitals and PGPs participating as downstream episode initiators as they were removed from decision-making, including when to exit the model. Further, convener participants are required to have financial guarantees that can impose significant upfront financial investment for participation.

2. CJR Participants

The participant structure of the CJR model is more straightforward than BPCI Advanced. Acute care hospitals in select metropolitan statistical areas are the only participants to trigger an episode and be held accountable for cost and quality performance. When CJR was implemented in 2016, we believed that the best policy approach was to assign financial accountability to large entities, such as hospitals, that care for a higher volume of Medicare beneficiaries. However, we recognized the importance of smaller entities, such as PGPs, and allowed gainsharing arrangements and other flexibilities to support collaboration with participating CJR hospitals.

3. Other Entities

Aside from hospitals and PGPs, other providers have signaled interest in managing or initiating clinical episodes. Expanding provider or participant eligibility may increase model scope, but it also adds operational complexity and reduces the likelihood of a seamless care experience for the beneficiary. For this reason, CMS attributes episodes to a single entity, regardless of the number of providers involved. Precedence rules generally dictate to which entity an episode of care is attributed, but these rules are often difficult for participants to follow. Data feeds inform entities of episode attribution when multiple providers have interacted with the beneficiary, but participants still express challenges with identifying their potential episodes due to lack of real-time data.

We request feedback on the following participant questions:

- Given that some entities may be better positioned to assume financial risk, what considerations should CMS take into account about different types of potential participants, such as hospitals and PGPs?

++ Should CMS consider flexibilities for PGPs to participate, such as a delayed start or a glide path to full financial risk?

++ How should CMS identify a PGP given the ability to form new practices and obtain new Tax Identification Numbers, and given the movement of suppliers within a PGP?

++ How can CMS ensure PGPs will remain engaged and accountable for their contributions to managing the episode of care?

- What concerns are there with conveners not being formal participants in this model since CMS cannot require entities that do not participate in the Medicare program?¹⁸

- Should CMS continue using precedence rules to attribute clinical episodes to a single accountable entity or consider weighted attribution for multiple accountable entities?

++ How could weighted attribution work?

++ How should incentives be structured to promote shared accountability and ensure program integrity?

D. Health Equity

Health equity is a pillar of the Biden Administration, as mentioned in Executive Order (E.O.) 13985, the HHS 2022-2026 Strategic Plan, and the CMS 2022 Strategic Plan, and it is one of the five objectives in the Innovation Center's 2021 Strategy Refresh.¹⁹ BPCI Advanced and CJR were designed prior to this more intentional focus on equity, but both models allow safety-net hospital participation and incorporate risk adjustment for dually eligible beneficiaries. We recognize there is room for improvement and intend to advance health equity through the design, implementation, and evaluation of this next episode-based payment model.

¹⁸ Participants could still choose to partner with a convening organization to receive similar services, such as data analytics or care navigators.

¹⁹ CMS Innovation Center Strategic Direction (<https://innovation.cms.gov/strategic-direction>) and CMS Strategic Plan (<https://www.cms.gov/cms-strategic-plan>).

The CJR 5th Annual Report and several independent studies display a widening, statistically significant gap between lower extremity joint replacement (LEJR) rates between the control group and CJR episodes and beneficiaries who are Black/African American and those who are white.^{20,21,22,23} While CJR potentially had an unfavorable impact on LEJR utilization rate, these studies acknowledge the presence of pre-existing disparities before the implementation of the CJR model. Future evaluations will capture the recent changes to the CJR risk adjustment methodology to include beneficiaries who are dually-eligible and the inclusion of safety-net hospitals. The impacts of these changes will inform the development and use of future risk adjustment strategies in episode-based models.

Improving access to high-quality, patient-centered care is a goal for the Innovation Center, and ensuring underserved beneficiaries are adequately represented in value-based care models may help reduce inequities when designed with the proper incentives. The BPCI Advanced Model's 4th Annual Report provides evidence that medical episodes may have greater reach to underserved populations than surgical episodes, because underserved populations are more likely to be admitted to a hospital due to a medical condition than due to a surgery.²⁴ Therefore, medical episodes may provide a greater opportunity to reach underserved beneficiaries in episode-based payment models, and by extension decrease discrepancies in care.

The Innovation Center is also committed to prioritizing the unique needs of providers who care for a large proportion of underserved populations. This includes flexibilities providers may need to be successful in future models. Further, to help address the increased social needs of

²⁰ CJR Fifth Annual Report (<https://innovation.cms.gov/data-and-reports/2023/cjr-py5-annual-report>).

²¹ Thirukumaran, C.P., Yeunkyung, K., Cai, X., C., Ricciardi, B.F., Yue, L., Fiscella, K.A., Mesfin, A., & Glance, L.G. (2021). Association of the Comprehensive Care for Joint Replacement Model with Disparities in the Use of Total Hip and Total Knee Replacement. *JAMA Network Open*, 4 (5), e2111858.

²² Ko, H., Martin, B.I., Nelson, R.E., & Pelt, C.E. (2022). Patient Selection in the Comprehensive Care for Joint Replacement Model. *Health Services Research*, 57, 72-90.

²³ Kim, H., Meath, T.H.A., Quiñones, A.R., McConnell, K.J., & Ibrahim, S.A. (2021). Association of Medicare Mandatory Bundled Payment Program with the Receipt of Elective Hip and Knee Replacement in White, Black, and Hispanic Beneficiaries. *JAMA Network Open*, 4 (3), e211772.

²⁴ BPCI Advanced's 4th Annual Report (<https://innovation.cms.gov/data-and-reports/2023/bpci-adv-ar4>) covers health equity findings from 2020-2021.

underserved populations, future episode-based payment models will need to consider the use of area level indicators, such as the social deprivation index (SDI), the social vulnerability index (SVI), and the area deprivation index (ADI).²⁵ These indicators would not only help address the increased social needs of beneficiaries, but would also help determine if additional risk adjustment variables would increase future models' reach to underserved groups.

To illuminate the potential health equity impacts of a new episode-based payment model and to help ensure the goals laid out in the CMS Strategic Plan and the Innovation Center Strategy Refresh are met, we request feedback on the following questions:

- What risk adjustments should be made to financial benchmarks to account for higher costs of traditionally underserved populations and safety net hospitals? (*Quality measurement is addressed more thoroughly in the next section of this RFI.*)

- Should episode-based payment models employ special adjustments or flexibilities for disproportionate share hospitals, providers serving a greater proportion of dually eligible beneficiaries, and/or providers in regions identified with a high ADI, SVI, or SDI?

- What other factors could be considered for providers who serve underserved beneficiaries or beneficiaries who experience social risk factors? Can measure stratification among patient subgroups and composite health equity measures improve how CMS identifies and quantifies potential disparities in care and outcomes?

- Based on the BPCI Advanced 4th Annual Report findings and the increased reach of medical episodes for underserved populations, should the next episode-based payment model have a larger focus on medical or surgical episodes?

- What metrics should be used or monitored to adjust payment to assure health disparities are not worsened as an unintended consequence?

²⁵ Refer to Table 2.1 in the Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments document (<https://aspe.hhs.gov/sites/default/files/documents/ce8cdc5da7d1b92314eab263a06efd03/Area-Level-SDOH-Indices-Report.pdf>) for descriptions of ADI, SDI, and SVI.

- Aside from claims data, what data sources would be valuable for evaluation and tracking of health equity?

++ What data or metrics or both should we share with participants to ensure they are addressing gaps in clinical outcomes and access to appropriate procedural care and with what frequency?

++ What data or metrics or both should we share publicly to help inform beneficiaries of provider performance?

- What provider-level initiatives or interventions, such as shared decision-making, could be considered to ensure equitable access to procedures and treatments for beneficiaries?

E. Quality Measures and Multi-payer Alignment

In accordance with section 1115A of the Social Security Act (the Act), the Innovation Center tests models that are expected to improve or maintain quality of care while reducing or maintaining program expenditures.²⁶ Current and prior models have used a combination of claims data, participant-reported or registry-based quality measures, and patient-reported outcome (PRO) measures to incentivize improvement and assess model and participant performance. To reduce provider burden, the Innovation Center is focused on including multi-payer alignment approaches, where feasible.

The CJR model assesses participant hospitals on a composite quality score, which is based on the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty measure (CBE#1550²⁷), the Hospital Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey measure (CBE#0166), and voluntary total knee and total hip arthroplasty PRO submission.

²⁶ Section 1115A of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm).

²⁷ In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the consensus-based entity more generally. See footnote 166 of the FY 2024 inpatient prospective payment systems (IPPS)/long-term care hospitals (LTCH) prospective payment system (PPS) proposed rule (88 FR 27025) (<https://www.federalregister.gov/documents/2023/05/01/2023-07389/medicare-program-proposed-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals>).

The BPCI Advanced model relies on care coordination across settings to improve quality and reduce costs for certain clinical episodes. Participants can choose to report a maximum of 5 measures under either the Administrative Quality Measure Set or Alternate Quality Measure Set. The Administrative Quality Measure set uses claims-based measures, including 3 required measures—Hospital-Wide All-Cause Unplanned Readmission Measure (CBE #1789), Advance Care Plan (CBE #0326), and CMS Patient Safety Indicators PSI 90 (CBE #0531)—and 3 additional measures which are appropriate for certain episodes. The Alternate Quality Measure Set requires reporting on the Hospital-Wide All-Cause Unplanned Readmission Measure (CBE #1789) and Advance Care Plan (CBE #0326) measures, and includes 23 more clinically-aligned measures appropriate for specific episodes. These measures are derived from registries and inpatient quality reporting, as well as claims.

The Innovation Center recently conducted a review of 21 Medicare models implemented between 2012 and 2020.²⁸ The evaluation, which examined relative performance on costs and quality, found two-thirds of the models demonstrated significant gross savings, but most showed no significant improvement in patient experience or mortality. Notably, the CJR model and surgical episodes managed by PGPs in the BPCI Advanced model significantly decreased readmissions, although neither model showed improvement in patient experience or reductions in emergency department use. The heterogeneity of quality measures used across models made relative assessment difficult and limited comparison to a handful of metrics for a subset of models. For example, self-reported experience of care was only measured in 12 of the 21 models.

CMS is committed to improving alignment across models and programs to simplify relative comparison of quality performance, to effectively track quality, outcomes, patient experience, and interoperable exchange of care data to generate evidence for determining

²⁸ The Synthesis of Evaluation Results Across 21 Medicare Models (<https://innovation.cms.gov/data-and-reports/2022/wp-eval-synthesis-21models>) highlighted that decreases in spending were most significant among acute and specialty care models, largely driven by lower utilization — 5 models reduced emergency department (ED) visits and 8 reduced inpatient readmissions.

whether, and to what extent, individual models improve care quality. This is in line with the broader CMS National Quality Strategy, including an effort to move toward digital quality measurement,²⁹ and recently announced plans to employ a “Universal Foundation” of quality measures to create greater consistency in primary care quality reporting.³⁰ As an extension of that aim, and with a particular focus on specialty care, the Innovation Center is considering how to increase the use of model-specific measures and adopt a more person-centered quality strategy, including greater use of PRO measures.

To that end, we are seeking feedback on how to best align quality measurement between new and established models and across payers, how other payers have approached quality measurement in episode-based models, and potential areas of alignment for a future episode-based payment model.

- Which quality measures, currently used in established models or quality reporting programs, would be most valuable for use across care settings?

- What quality measures are other payers using to drive improvements in clinical episodes?

- What PRO measures should CMS consider including in this next episode-based payment model?

++ Are payers testing or finding success with any PRO measures in existing episode-based models?

- In what specific measurement areas can CMS improve upon the current Inpatient Quality Reporting and Value-Based Purchasing measure sets³¹ to better capture performance on

²⁹ dQM Strategic Roadmap (<https://ecqi.healthit.gov/dqm>).

³⁰ Jacobs, D. B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L. A. (2023). Aligning Quality Measures across CMS – The Universal Foundation. *New England Journal of Medicine*, 388 (9), 776-779. DOI: 10.1056/NEJMp2215539.

³¹ The Acute Care Hospital Quality Improvement Program Measures FY 2025 reference guide (<https://qualitynet.cms.gov/inpatient/iqr/measures>) provides a comparison of measures for five CMS acute care hospital quality improvement programs.

acute medical and surgical episodes and the interoperable exchange of patient data between coordinating providers?

- The CAHPS® for the Merit-based Incentive Payment System (MIPS) includes questions to assess the degree to which shared decision-making has been implemented in the outpatient setting. How can CMS most effectively measure these activities in the hospital setting?

- What supports can this new model provide for decreasing burden of data collection?

- ++ How can registries, electronic health records, and other quality reporting systems reduce reporting burden for participants?

- ++ What approaches are providers currently utilizing that would create opportunities for payer alignment?

- ++ Are there opportunities to reduce provider burden across episodes through multi-payer alignment of quality measures and social risk adjustment?

F. Payment Methodology and Structure

Payment methodology is a key element of an episode-based payment model. While there are notable differences between the CJR and BPCI Advanced payment methodologies, the models are built on a similar underlying payment structure wherein participants receive preliminary target prices prior to the performance period, are paid through the traditional Medicare FFS payment systems during a performance period, and are subject to a retrospective payment reconciliation calculation after the performance period. This reconciliation calculation compares the participant's FFS spending to an adjusted target price, with the participant either earning a reconciliation payment or owing a repayment to Medicare. This retrospective reconciliation process avoids the need for changes to Medicare FFS claims-processing systems and for participants to pay downstream providers who deliver services during the episode, as is done with prospective model payments. However, both models have been subject to challenges

with regard to various aspects of the payment methodology, including reconciliation timing, target price methodology, and risk adjustment.

1. Reconciliation Timing

CMS has tried to balance participants' desire to receive reconciliation results as close as possible to the performance period, while also allowing for sufficient claims runout to finalize the results and minimize the administrative burden of multiple reconciliations. Still, participants have indicated difficulty investing in and maintaining care redesign activities, as the incentive payments that support these activities are paid well after they have occurred. Reconciliation timing for BPCI Advanced, CJR, and the CJR extension are summarized in Table 1.

TABLE 1. COMPARISON OF RECONCILIATION TIMING

	BPCI Advanced Model Years (MYs) 1-8	CJR Performance Years (PYs) 1-5	CJR Extension PYs 6-8
Performance Period	6 months	1 year ³²	1 year ³³
Number of Reconciliations per Performance Period	3	2	1
Approximate Claims Runout (from last episode)	3 months, 9 months, 15 months	2 months, 14 months	6 months

2. Target Prices

Reconciliations are based on comparison of performance period spending and the target price for a given participant and episode. The method of calculating target prices has changed over time for both CJR and BPCI Advanced, as CMS has sought to balance the need for predictable and achievable target prices with the need to respond to market changes and allow a reasonable likelihood of overall Medicare savings. Key features of the target price methodology for BPCI Advanced, CJR, and the CJR extension are summarized in Table 2.

³²With the exception of years impacted by COVID.

³³ With the exception of years impacted by COVID.

TABLE 2. COMPARISON OF TARGET PRICING

	BPCI Advanced (MYs 1-3)	BPCI Advanced (MYs 4-8)	CJR (PY 1-5)	CJR extension (PY 6-8)
Baseline Claims Period	4 years	4 years	3 years	1 year
Frequency of Baseline Update	Annual	Annual	Every 2 years	Annual ³⁴
Baseline Claims Blend	Participant Historical Claims, Patient Case Mix, Peer Group Characteristics, Peer Group Trends	Participant Historical Claims, Patient Case Mix, Peer Group Characteristics, Peer Group Trends	PY 1-2: 2/3 Participant, 1/3 Regional PY 3: 1/3 Participant, 2/3 Regional PY 4-5: Regional Only	Regional Only
Adjustments at Reconciliation	Patient Case Mix Adjustment, Quality Adjustment	Patient Case Mix Adjustment, Peer Group Trend Factor Adjustment, Quality Adjustment	Quality Adjustment	Regional Market Trend Factor, Normalization Factor, Quality Adjustment

The CJR and BPCI Advanced models initially used a prospective trend methodology to project future episode spending to construct target prices. However, early reconciliation results from both models, combined with nationwide spending data, suggested that the prospective trend had not accurately captured national changes in spending patterns during the model performance period, resulting in reconciliation payments that were higher than needed to incentivize care coordination. To more accurately reflect performance period episode costs and to help minimize the risk that the models increased spending, CMS incorporated a retrospective trend into the target price methodology for both models, allowing for a target price adjustment at reconciliation.³⁵ However, a number of BPCI Advanced participants found the retrospective trend untenable, given the unpredictability and resulting challenge of gauging their performance in the model. The retrospective trend for most episodes was lower than the prospective trend had been in previous years, resulting in a downward adjustment to target prices at reconciliation and leading many participants to withdraw from the model.

3. Risk Adjustment

CMS recognizes that patients will require various levels of care, with differences in appropriate episode spending based on a number of factors. To acknowledge this variability and

³⁴ With the exception of PY 7, which repeated the use of 2019 data as baseline in order to avoid the impact of COVID in 2020 data.

³⁵ Under section 1115A(b)(3)(B) of the Social Security Act, the CMS Innovation Center has a statutory obligation to modify or terminate models unless the model is expected to improve quality without increasing spending, reduce spending without reducing quality, or improve quality and reduce spending after testing has begun.

minimize the likelihood of participants preferentially selecting healthier patients for treatment in the model (also known as “cherry picking”), CMS has included risk adjustment in both the CJR and BPCI Advanced payment methodologies. Factors used in risk adjustment are summarized in Table 3.

TABLE 3. COMPARISON OF PATIENT-LEVEL RISK ADJUSTMENT FACTORS

BPCI Advanced (MY 1-8)³⁶	CJR (PY 1-5)	CJR extension (PY 6-8)
MS-DRG/APCs,³⁷ age, dual eligibility status, disability as reason for Medicare eligibility, Hierarchical Condition Categories (HCCs), HCC count, recent health service resource use	MS-DRG, hip fracture ³⁸	MS-DRG/HCPCS, ³⁹ age group, dual eligibility status, CJR HCC count

Risk adjustment in Innovation Center episode-based models is largely based on CMS claims and enrollment data. However, beneficiary characteristics from other sources, such as electronic health records or non-medical determinants of health, are not accounted for by the use of claims and enrollment data. CMS is considering ways to incorporate non-claims-based variables, if collected uniformly and documented consistently, to improve risk adjustment and address health equity. Interested parties have also recommended the inclusion of trigger event diagnosis codes to better capture beneficiary acuity. However, we are concerned that risk adjusting based on variables that occur contemporaneous to the episode could incentivize increased coding intensity.

4. Alternative Payment Approach

In light of the CJR and BPCI Advanced payment methodology challenges, we are considering changes to our payment approach, such as incorporating elements of value-based purchasing. Under a value-based purchasing framework, participants are assessed on certain

³⁶ While the patient characteristics used in risk adjustment has remained fairly consistent across Model Years, please see the BPCI Advanced Model Year 6 Target Prices Specifications (<https://innovation.cms.gov/media/document/bpci-adv-targetprice-specs-my6-mar2023>) for the most updated and complete list.

³⁷ Medicare Severity Diagnosis Related Group/Ambulatory Payment Classifications.

³⁸ The FY 2021 IPPS/LTCH final rule (85 FR 58432) created two new MS-DRGs that separated hospital discharges for LEJR with hip fracture (521, 522) from those without hip fracture (469, 470). CJR added these MS-DRGs to the model, which removed the need for an additional risk adjustment for hip fracture.

³⁹ Medicare Severity Diagnosis Related Group/Healthcare Common Procedure Coding System.

measures and their future Medicare FFS payments are adjusted up or down based on their performance. For instance, the Hospital Value Based Purchasing (VBP) program withholds 2% of the base operating MS-DRG payments of participating hospitals, and then redistributes those funds to hospitals in a future year via a payment adjustment based on their Total Performance Score across four domains (Clinical Outcomes, Person and Community Engagement, Safety, and Efficiency and Cost Reduction). Similarly, in the traditional Merit-based Incentive Payment System (MIPS), clinicians submit data on four domains (Quality, Promoting Interoperability, Improvement Activities, and Cost), and the MIPS final score determines a payment adjustment to future Medicare Part B claims. To avoid duplicating the existing value-based purchasing initiatives, we are considering blending the traditional payment approach by setting a target price but paying the reconciliation payment (or recouping the repayment amount) in future years as a multiplier or add-on to future claims, rather than as a lump sum at the time of the reconciliation calculation. We anticipate that incorporating value-based purchasing design components could help to resolve concerns with pricing predictability and remove the operational burdens of the reconciliation process. We recognize this alternative approach, along with other payment methodology features, would require input from interested parties. Therefore, we request feedback on the following payment methodology questions.

- How should CMS balance the need for predictable, achievable target prices with the need to create a reasonable possibility of achieving net Medicare savings?
- How should CMS balance participants' desire to receive reconciliation results as close as possible to the performance period, while also allowing for sufficient claims runout to finalize the results and minimize the administrative burden of multiple reconciliations?
- How should risk adjustment be factored into payment for episode-based payment models?
- ++ How can risk adjustment be designed to guard against preferential selection of healthier patients (that is, cherry picking)?

++ What risk factors, including clinical or social, should be considered?

++ Which non-claims-based variables could be used to improve risk adjustment and address health equity, and how can CMS ensure that they are collected uniformly and documented consistently?

++ How can CMS account for apparent changes in risk that are actually due to changes in coding patterns rather than changes in health status?

- If CMS were to move toward a value-based purchasing approach for acute care episodes, what performance measures (including quality and utilization or cost measures) should participants be accountable for?

++ What level of payment adjustment to future claims would be sufficient to balance the need to: (1) incentivize coordination with physician group practices and post-acute care providers; (2) achieve savings or budget neutrality for Medicare; and (3) create a reasonable, but not onerous, level of downside risk for participants?

++ To what extent could quality measures already collected in existing value-based programs (for example, MIPS, MIPS Value Pathways (MVPs), post-acute care VBPs) be incorporated into an acute care episode-based payment model?

- How could CMS incorporate other non-claims-based variables, such as from electronic health records or non-medical determinants of health, to improve risk adjustment, care coordination, quality measurement, and/or address health equity?

G. Model Overlap

The Innovation Center Strategic Refresh highlights the need to streamline the Innovation Center's model portfolio, reduce complexity, and capture broad provider participation.⁴⁰ These lessons learned resonate when considering the challenges between the interactions of episode-based payment models and ACO initiatives. While CMS continues to learn from tested

⁴⁰ CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation - A Strategy for the CMS Innovation Center's Second Decade (<https://innovation.cms.gov/strategic-direction-whitepaper>).

policies, none have consistently encouraged overlap or promoted meaningful collaboration between primary care and specialty care providers. Overlap policies were intended to avoid duplicative incentive payments or give precedence to a single accountable entity. In some cases, these policies resulted in confusing methodologies or misaligned incentives which were difficult for providers to navigate. Providers have also cited confusion with identifying to which model(s) a beneficiary may be aligned or attributed.

1. Duplicate Payments

In earlier episode-based payment models, such as CJR (when applicable) and BPCI, CMS addressed overlap by implementing a complex calculation and recouping a portion of the pricing discount for providers participating in certain ACO initiatives. The recoupment was intended to prevent duplicate incentive payments for the same beneficiary's care. Yet some participants perceived the recoupment as a financial penalty, discouraging providers from participating in both initiatives. To avoid complexity, the CJR and BPCI Advanced models exclude overlap for beneficiaries aligned or assigned to certain ACOs, and these beneficiaries will not initiate a clinical episode.⁴¹

While this exclusionary approach creates a clean demarcation of who is accountable for a beneficiary's care, it also limits the number of providers in accountable care relationships and becomes less tenable as we work towards the goal of increased accountability. Additionally, participants may be informed of beneficiary ACO alignment or assignment after the potential episode has been initiated and after the participant has expended resources for items or services not covered by Medicare on unattributed beneficiaries. This concern highlights the opportunity to incentivize coordinated care, expand care redesign efforts to more patients, and strengthen APM participation. Lastly, even passive avoidance of duplicate payments has its drawbacks such

⁴¹ Currently, the BPCI Advanced model does not allow overlap with the ACO Realizing Equity, Access, and Community Health (ACO REACH) model, the Vermont All-Payer ACO Model, and the Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices (KCC) Model. The CJR model does not allow overlap with the ENHANCED Track of the Medicare Shared Savings Program.

as lack of incentive to coordinate care. For example, the CJR and BPCI Advanced models allow overlap with the Medicare Shared Savings Program without a financial recoupment.^{42,43} However, this does not encourage behavior change to ensure a smooth transition back to population-based providers.

2. Overlap

Both episode-based payment models and ACOs have demonstrated successes in reducing post-acute care spending through reductions in skilled nursing facility length of stay or reduced institutional post-acute care use.^{44,45} However, when the same beneficiary is included in both an ACO initiative and episode-based payment model, it may create confusion and inefficiencies. Providers in both models invest in care management and rely on the savings generated to support these functions. If those spending reductions are credited to only one of these entities, this may create a barrier for collaboration. Further, if an episode of care is priced too high, this can negatively impact the ACO's financial performance and add to inefficiencies between episode-based payment models and ACOs.

Regardless of the issues identified, evidence suggests shared beneficiaries in episode-based payment models and ACOs can lead to lower post-acute care spending and reduced readmissions.⁴⁶ In light of findings like this, we believe overlap with episode-based payment models and ACOs should be supported through complementary policies. We want to avoid precedence or exclusionary rules for entities who may be required to participate in this next episode-based payment model. This means all of the participating entity's beneficiaries for a

⁴²The Medicare Shared Savings Program benchmark updates include retrospective county-level trends that implicitly reflect BPCI Advanced and CJR spending changes; such methodology helps mitigate potential overlap of federal outlays.

⁴³ The CJR model only allows overlap with the BASIC track of the Medicare Shared Savings Program.

⁴⁴ Comprehensive Care for Joint Replacement Model: Fourth Evaluation Report; BPCI Advanced: Fourth Annual Report (<https://innovation.cms.gov/data-and-reports/2021/cjr-py4-annual-report>).

⁴⁵ McWilliams, J. M., Gilstrap, L. G., Stevenson, D. G., Chernew, M. E., Huskamp, H. A., & Grabowski, D. C. (2017). Changes in Postacute Care in the Medicare Shared Savings Program. *JAMA internal medicine*, 177(4), 518–526. doi:10.1001/jamainternmed.2016.9115.

⁴⁶ Navathe, A. S., Liao, J. M., Wang, E., Isidro, U., Zhu, J., Cousins, D. S., & Werner, R. M. (2021). Association of Patient Outcomes With Bundled Payments Among Hospitalized Patients Attributed to Accountable Care Organizations. *JAMA health forum*, 2(8), e212131. <https://doi.org/10.1001/jamahealthforum.2021.2131>.

given clinical episode or service line group may be eligible to initiate an episode regardless of beneficiary ACO assignment/alignment. This may help the participant create standard care pathways for all beneficiaries and make it easier for ACOs to know which beneficiaries may be initiating a clinical episode. We also want to encourage overlap between this next model and ACO initiatives to support coordination and ensure providers are not carved out of a beneficiary's continuum of care. This means we must account for duplicate payments when there are shared beneficiaries. We are considering simple ways a target price can be factored into an ACO's benchmark, or how the target price can be adjusted to account for shared beneficiaries so that providers in both models have financial incentives to drive efficiency and coordinate care. We aim to resolve the previous model overlap challenges and request feedback for the following model overlap questions:

- How can CMS allow beneficiary overlap with ACO initiatives yet ensure Medicare is not double-paying incentives for the same beneficiary?

- ++ Should the approach to prevent double-paying incentives differ depending on whether the participating entity is part of an ACO or particular type of ACO (for example, low revenue ACOs vs. high revenue ACOs, or one-sided vs. two-sided risk ACOs)?

- ++ What are the implications of allowing beneficiary overlap for model evaluation?

- How should CMS create a reciprocal overlap policy that incentivizes efficiency by the participant while the ACO is incentivized to use the participant for episodic care?

- ++ What risks or rewards should we include to drive collaboration?

- ++ What resources or data should CMS provide participants to ensure there is collaboration with ACO providers for shared beneficiaries?

- ++ What resources or data should CMS provide ACOs to ensure collaboration with participants for shared beneficiaries? How does this differ when the participant is not part of the ACO?

- How can CMS leverage this episode-based payment model to incentivize participants to join an ACO if not already a part of one?

++ Conversely, how can this episode-based payment model incentivize ACOs to partner with participants?

- How does CMS ensure episode spending aligns with ACO benchmarks, especially if ACO benchmark methodology changes?

- What levers, such as benefit enhancements or waivers, could be used to support participants to close the care loop back to primary care/ACOs?

- How can CMS design this model to spur ACOs to engage specialty care providers for episodes of care that may not be included in this model?

III. Collection of Information Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that this is a RFI only. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not

responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this document are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 11, 2023.

Dated: July 13, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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